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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,020	01/09/2006	Irene Bozzoni	2312.001US1	7176
21186 7590 11/25/2009 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
EXAMINER				
CHONG, KIMBERLY				
ART UNIT		PAPER NUMBER		
1635				
NOTIFICATION DATE		DELIVERY MODE		
11/25/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com  
request@slwip.com

### Office Action Summary

**Application No.**

10/564,020

**Applicant(s)**

BOZZONI ET AL.

**Examiner**

KIMBERLY CHONG

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response 07/02/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 04/03/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 07/02/2009, claims 1-7 are pending and currently under examination in the application.

### ***Re: Claim Rejections - 35 USC § 103 - maintained***

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Kreutzer et al. (US 20040001811 of record cited on PTO 892 mailed 08/18/2008), Elbashir et al. (Methods 2002, Vol. 26: 199-213 of record cited on PTO 892 mailed 08/18/2008), Nilsen et al. (US Patent No. 6013447), De Young et al. (Biochemistry 1994, cited in IDS filed 11/20/2008), Hernandez (EMBO 1985, Vol. 4, No. 7: 1827-1837 of record cited on PTO 892 mailed 08/18/2008) and Skuzeski et al. (JBC 1984, Vol. 259, NO. 13: 8345-8352 of record cited on PTO 892 mailed 08/18/2008) is maintained for the reasons of record.

Applicant's arguments filed 07/02/2009 have been fully considered but they are not persuasive. Applicant argues Kreutzer et al. mention a U1 snRNA promoter but teaches a pol III promoter as a preferred promoter and do not teach the dsRNA having the end structure as claimed and further argues Elbashir et al. do not teach siRNA having UU overhang regions. Applicant states the Examiner incorrectly points to column 13 of Nilsen et al. for teaching U1 snRNA promoters and terminations sequences. Applicant summarized the teachings of De Young et al., Hernandez et al. and Skuzeski et al. but do not provide arguments regarding why these references in combination with Kreutzer et al. and Elbashir et al. do not render the claimed invention obvious. Applicant concludes that none of the cited references employ a U1 promoter to produce siRNA or mRNA from a vector as claimed and do not teach such advantages as accepting U sequences in the transcribed region or that primary transcripts derived are efficiently exported to the cytoplasm etc.

These arguments are not convincing. Applicant has not provide any arguments that would render the claimed invention non-obvious and has not provided any evidence of unexpected results such that it would not be obvious to make the claimed invention. Regarding the arguments against Kreutzer et al., a reference is relied upon for all that it teaches even non-preferred embodiments. Kreutzer et al. teach dsRNA can be expressed from an expression vector wherein the siRNA is transcribed by promoter and expressed as an inverted repeat joined by a linker polynucleotide such that the siRNA has a stem and loop structure and teach the use several types of promoters including U1 snRNA pol II promoters. The use of any one particular promoter would be a design

choice by one of ordinary skill in the art and given De Young et al. teach the advantages of using an expression vector system comprising a U1 promoter for expression of inhibitory molecules such as ribozymes, it would have been obvious to use this vector for expression of a dsRNA.

With regard to Applicant's argument that Elbashir et al. not teach a siRNA comprising overhang regions comprising UU, this argument is incorrect. On page 201 in the last paragraph, Elbashir et al. teach the preference for target regions that allow for siRNA sequences that contain uridine residues in the overhang regions and state the overhang regions *can be* replaced by 2'-deoxythymidine but does not require such. Moreover, the prior art is replete with dsRNA molecules comprising various end structures, including UU.

Applicant misinterprets the Examiner's explanation of the teachings of Nilsen et al. Nilsen et al. teach the use of an expression vector for expressing small inhibitory RNAs, such as antisense and ribozymes, comprising U1 snRNA pol II promoters and teach such expression units preferably comprise termination sequences. Thus, Nilsen et al. teach the use of expression vectors that preferably comprise termination sequences and it was not stated that Nilsen et al. specifically teach an expression vector comprising a snRNA promoter and a termination sequences. Nilsen et al. was cited for the motivation to incorporate a termination sequence into an expression vector.

While it is true that none of the documents teach a specific embodiment of an expression vector comprising a U1 promoter, the references in combination teach that it would have been obvious to one of ordinary skill in the art to make an expression vector

capable of expressing a siRNA wherein the siRNA comprises 3' UU overhangs and a IU promoter as taught by Elbashir et al. and Kreutzer et al. and that it would have further been obvious to incorporate the elements taught by Nilsen et al. and Hernandez, such as the 3' end termination sequence and further to clone the U1 snRNA promoter into the expression vector using a Bgl II restriction site for the reasons taught by Skuzeski et al. Moreover, none of the advantages of the claimed expression vector as argued by Applicant in the last paragraph of the remarks is cited in the instant claims.

Thus, the rejection is maintained for the reasons stated above and of record.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-

Art Unit: 1635

3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Tracy Vivlmore at 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1635